FORM APPROVED OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	02-001	Washington
FOR: HEALTH CARE FINANCING ADMINISTRATION	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE January 1, 2002	
5. TYPE OF PLAN MATERIAL (Check One):	CONGIDEDED AGNEWAY AN	₩ ANGENIDAGNIT
	CONSIDERED AS NEW PLAN	AMENDMENT
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AME: 6. FEDERAL STATUTE/REGULATION CITATION:	7. FEDERAL BUDGET IMPACT:	amenament)
	a. FFY 2002 (\$ 6,225,000) b. FFY 2003 (\$10,000,000)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERS OR ATTACHMENT (If Applicable):	
Attachment 3.1-A	Attachment 3.1-A	
Pages 5-1 and 5-2 pages 5-1 through 5-3 (Prt)	Page 5-1	
Attachment 3.1-B	Attachment 3.1-B	
Pages 4-1 and 4-2 and 4-3 (P+1)	Page 4-1	
Pages 4-1 and 4-2 and 4-3 (P+I) artainment 4:19 B. payes 2-b and 2-c (P+I) Sup. A to attainment 4:19B. page 1 with supplementa 10. SUBJECT OF AMENDMENT:	repate garcement (P+T)	
10. SUBJECT OF AMENDMENT:		
Prescription Drugs		
11. GOVERNOR'S REVIEW (Check One): GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	☑OTHER, AS SPEC	IFIED: Exempt
12 SIGNATURE OF STATE AGENCY OF PICIAL: //	16. RETURN TO:	
De bull	Department of Social and Health Ser	rvices
13. TX PED NAME:	Medical Assistance Administration	
DENNIS BRADDOCK	623 8 th St SE MS: 45500	
14. TITLE:	Olympia, WA 98504-5500	
Secretary	, , , , , , , , , , , , , , , , , , , ,	
15. DATE SUBMITTED:		
FOR REGIONAL OF	FICE USE ONLY	
17. DATE RECEIVED: JAN 1 2002	18. DATE APPROVED: SEP 16	2002
PLAN APPROVED - ONI		Color Color
19. EFFECTIVE DATE OF APPROVED MATERIA - 1 2002	20. SIGNATURE OF REGIONAL OFF	ICIAL:
21. TYPED NAME: Butterfield	Pos Recipal Rd	ministrator
23. REMARKS: P+I Changes authorized by t Central Office on 9/16/02.	ne State - approved	iby ems
	(CAVATAL)	

a. Prescribed Drugs

Drug Coverage

- (1) Covered outpatient drugs as defined in Section 1927 (k)(2) of the Act are those which are prescribed for a medically accepted indication and produced by any manufacturer, which has entered into and complies with an agreement under Section 1927(a) of the Act.
- (2) Prescriptions written as a result of an EPSDT visit will be approved as ordered by the prescriber when that information is communicated to the TCS clinical pharmacists.
- (3) Generic drugs, insulin and diabetic supplies, contraceptives, antipsychotics, anticonvulsants, antidepressants, chemotherapy, antiretrovirals, immunosuppresants and hypoglycemic rescue agents will be exempt from triggering a TCS review. During a TCS review, all covered outpatient drugs, as defined in Section 1927 (k) (2) of the Act will be authorized for the Medicaid client, if the prescriber deems them to be medically necessary.
- (4) Under Washington Administrative Code, pharmacies are advised to provide an emergency supply of medically necessary drugs when TCS reviews are pending.
- (5) Drugs excluded from coverage as provided by Section 1927(d) (2) of the Act, include: DESI drugs, experimental drugs; weight loss drugs (unless prescribed for an indication other than obesity), drugs for cosmetic purposes, drugs for fertility and drugs for smoking cessation (except that Zyban is covered for pregnant or post-partum women according to Washington Administrative Code).

Prior Authorization

- (6) Prescription drugs may be subject to prior authorization by the agency to ensure that drugs are prescribed and dispensed appropriately.
- (7) MAA determines which prescription drugs may require prior authorization by reviewing the drug(s) for the following:
 - Safety
 - · Potential for abuse or misuse
 - Narrow therapeutic index.
 - High cost when less expensive alternatives are available

TN# 02-001 Supercedes TN# 95-16 Approval Date:

12. a. Prescribed Drugs (Cont.)

(8) Prior authorization programs for covered outpatient drugs provide for a response within 24 hours of a request for prior authorization and provides for the dispensing of at least a 72-hours supply of medications in emergency situations.

Therapeutic Consultation Service (TCS)

(9) In the Therapeutic Consultation Service (TCS), all Medicaid recipients will have their entire drug profile reviewed by clinical pharmacists after the fifth request for a brand-name drug is processed in a calendar month or anytime a request for a non-preferred drug is processed. A non-preferred drug is a drug in a drug class that has essentially the same clinical safety and efficacy as the drug of choice, but is not the preferred drug. TCS is not a limit, but rather a service to provide a clinical pharmacy review of the client's entire drug therapy. This review is conducted to assure that Medicaid clients are receiving appropriate drug therapy, without therapeutic duplication or without potentially serious drug-drug interactions or drug-disease conflicts. Prescribers direct clients' drug therapy and have the final say. Reports will be available that indicate the numbers of prescriptions that were dispensed as originally ordered by the prescriber.

Supplemental Rebate Agreement

- (10) The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:
 - Manufacturers are allowed to audit utilization rates;
 - The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927 (b)(3)(D); and
 - Rebate agreements between the state and a drug manufacturer that
 are separate from the drug rebate agreements of Section 1927 are
 approved by the Centers for Medicare and Medicaid Services. The
 state reports rebates from separate agreements to the Secretary for
 Health and Human Services. The state will remit the federal portion
 of any cash state supplemental rebates collected.

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b. Dentures

Prior approval for cast base partial dentures

- c. Prosthetic devices
 - (1) Prior approval
 - (2) Hearing aids provided on the basis of minimal decibel loss
- d. Eyeglasses
 - (1) Contact lenses and two pairs of glasses in lieu of bifocal or trifocal lenses require prior approval.
 - (2) Sunglasses, photochromatic or varilux type lenses and orthoptic therapy are not provided.
 - (3) Group screening for eyeglasses is not permitted.
 - (4) Limited to one refraction and one pair of glasses in a twelve-month period except in extenuating circumstances when medically necessary.
- 13 a Diagnostic Services

As needed and approved

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- 8. Private duty nursing services
 - (1) Require prior approval.
 - (2) Must be provided by a registered nurse or licensed practical nurse.
 - (3) Must be under the direction of a physician.
 - (4) Limited to a non-institutional setting.
- 10. Dental services
 - (1) Limited to medically necessary treatment for relief of pain and infection, restoration of teeth, and maintenance of dental health.
 - (2) Orthodontic treatment is limited to recipients of EPSDT.
- 11. Physical therapy and related services
 - a. Physical therapy

Allowed as an inpatient hospital service or when provided by a home health agency. Period of home health agency service reviewed and limited by the state.

b. Occupational therapy

Allowed as an inpatient hospital service or when provided by a home health agency. Period of home health agency service reviewed and limited by the state.

12. a. Prescribed Drugs

Drug Coverage

- (1) Covered outpatient drugs as defined in Section 1927 (k)(2) of the Act are those which are prescribed for a medically accepted indication and produced by any manufacturer, which has entered into and complies with an agreement under Section 1927(a) of the Act.
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12. Prescribed Drugs, Drug Coverage (Contd) a.

- Generic drugs, insulin and diabetic supplies, contraceptives. (3)antipsychotics, anticonvulsants, antidepressants, chemotherapy, antiretrovirals, immunosuppresants and hypoglycemic rescue agents will be exempt from triggering a TCS review. During a TCS review, all covered outpatient drugs, as defined in Section 1927 (k) (2) of the Act will be authorized for the Medicaid client, if the prescriber deems them to be medically necessary.
- (4) Under Washington Administrative Code, pharmacies are advised to provide an emergency supply of medically necessary drugs when TCS reviews are pending.
- Drugs excluded from coverage as provided by Section 1927(d) (2) of the (6) Act, include: DESI drugs, experimental drugs; weight loss drugs (unless prescribed for an indication other than obesity), drugs for cosmetic purposes, drugs for fertility and drugs for smoking cessation (except that Zyban is covered for pregnant or post-partum women according to Washington Administrative Code).

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- (8) MAA determines which prescription drugs may require prior authorization by reviewing the drug(s) for the following:
 - o Safety
 - o Potential for abuse or misuse
 - Narrow therapeutic index
 - o High cost when less expensive alternatives are available
- (9) Prior authorization programs for covered outpatient drugs provide for a response within 24 hours of a request for prior authorization and provides for the dispensing of at least a 72-hours supply of medications in emergency situations.

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In the Therapeutic Consultation Service (TCS), all Medicaid recipients will (10)have their entire drug profile reviewed by clinical pharmacists after the fifth request for a brand-name drug is processed in a calendar month or anytime a request for a non-preferred drug is processed. A nonpreferred drug is a drug in a drug class that has essentially the same clinical safety and efficacy as the drug of choice, but is not the preferred

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12. a. Prescribed Drugs Therapeutic Consultation Service (Cont.)

drug. TCS is not a limit, but rather a service to provide a clinical pharmacy review of the client's entire drug therapy. This review is conducted to assure that Medicaid clients are receiving appropriate drug therapy, without therapeutic duplication or without potentially serious drug-drug interactions or drug-disease conflicts. Prescribers direct clients' drug therapy and have final approval. Reports will be available that indicate the numbers of prescriptions that were dispensed as originally ordered by the prescriber.

Supplemental Rebate Agreement

- (10) The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:
 - Manufacturers are allowed to audit utilization rates:
 - The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927 (b)(3)(D); and
 - Rebate agreements between the state and a drug manufacturer that
 are separate from the drug rebate agreements of Section 1927 are
 approved by the Centers for Medicare and Medicaid Services. The
 state reports rebates from separate agreements to the Secretary for
 Health and Human Services. The state will remit the federal portion
 of any cash state supplemental rebates collected.

4. The single state agency shall determine EAC by periodically determining the pharmacies' average acquisition costs for a sample of drug codes. The average cost shall be based on in-state wholesalers' published prices to subscribers, plus an average upcharge, if applicable. The single state agency shall pay the EAC for a multiple-source product if the EAC is less than the MAC/AMAC established for that product.

C. Upper Limits for "Other" drugs:

- An "other" drug is defined as a brand name (single source) drug, a 1. multiple-source drug where significant clinical differences exist between the branded product and generic equivalents, or a drug with limited availability.
- 2. Payments for "other" drugs are based on Average Wholesale Price (AWP) less a specified percentage. AWP is determined using price information provided by the drug file contractor.
- 3. See Supplement A for current EAC percentages.

D. Dispensing Fee Determination:

- The department sets pharmacy dispensing fees based on results of 1. periodic surveys.
- 2. The current dispensing fee payment system is multi-tiered. The dispensing fee paid to a pharmacy depends upon that pharmacy's total annual prescription volume (both Medicaid and non-Medicaid), as reported to the department.
- 3. Pharmacies providing unit dose delivery service are paid the department's highest allowable dispensing fee for unit dose prescriptions dispensed. All other prescriptions filled by these pharmacies are paid at the dispensing fee level applicable to their annual prescription volume.

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Supercedes

- 4. A dispensing fee is paid for each ingredient in a compound prescription.
- 5. See Supplement A for current dispensing fees.

REIMBURSEMENT FOR PHARMACY SERVICES

- Estimated Acquisition Cost (EAC)
 - A. First DataBank derives the Average Wholesale Price (AWP) of each product based on information they receive directly from each manufacturer or labeler. The appropriate percentage of the AWP that represents the Estimated Acquisition Cost (EAC) is determined. Most drugs are reimbursed at the EAC plus a dispensing fee.
 - B. Currently applied EAC percentages are:
 - Schedule II drugs......100% of AWP
 - All others......89% of AWP

V. Dispensing Fees

- A. A three-tier dispensing fee structure is used, with an adjusted fee allowed for pharmacies that participate in the Modified Unit Dose and/or True Unit Dose programs.
- B. Listed below are the dispensing fee allowances for pharmacies (effective 7/1/01):
 - High-volume pharmacies (over 35,000 Rxs/yr)...........\$4.14/Rx

 - Low volume pharmacies (15,000 Rxs/yr and under).....\$5.12/Rx
- C. A provider's dispensing fee is determined by the volume of prescriptions the pharmacy fills for medical assistance clients and the general public, as indicated on the annual prescription count survey distributed to pharmacies.

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TN# 02-001 Supercedes TN# ----- SEP 16 Effective Date: 1/1/02

SUPPLEMENTAL REBATE AGREEMENT

This Supplemental Rebate Agreement ("Agreement") is dated as of this d	lay of
, 200_, by and between the State of Washington Department	of Social and
Health Services ("State") and (name of provider).	

RECITALS

WHEREAS, the State has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates for the benefit of the State's Medicaid recipients providing such agreements are approved by the Center for Medicare and Medicaid Services (CMS); and

WHEREAS, (name of provider) is willing to provide supplemental rebates to the State based on the actual dispensing of (name of provider) Covered Products under the State's Medicaid program.

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties, intending to be legally bound, agree as follows:

- 1. **Definitions.** As used herein, the following terms shall have the meanings set forth below:
- 1.1 "Agreement" means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.
- 1.2 "Average Wholesale Price ("AWP")" shall mean the published price of the Covered Product by National Drug Code ("NDC") as published by First DataBank on the first day of the calendar quarter that corresponds to the calendar quarter for which the State utilization data for the Covered Product is reported to (name of provider).
- 1.3 "Basic Rebate" shall mean, with respect to the Covered Product, the quarterly payment by (name of provider) pursuant to (name of provider's) Medicaid Drug Rebate
 Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).
- "CMS" shall mean the Center for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.
- 1.5 "Competitive Product" shall mean (specific product(s)), (e.g., "any Proton Pump Inhibitor ("PPI") that competes with Covered Product. PPI's are defined as PRILOSEC® (omeprazole), ACIPHEX TM (rabeprazole sodium), PROTONIX® (pantoprazole sodium), NEXIUMTM (esomeprazole magnesium), and any other branded PPI approved by the FDA during the term of this Agreement.")
- 1.6 "Covered Product" shall mean (specific product(s), e.g., "Prevacid (lansoprazole) 15mg and 30mg capsules.")

- "CPI Rebate" means, with respect to the Covered Product, the quarterly payment by (name of provider) pursuant to (name of provider's) Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).
- 1.8 **"Ingredient Reimbursement Basis"** shall mean the formula used by State to reimburse Pharmacy providers for branded pharmaceuticals.
- 1.9 "Maximum Allowable Cost (MAC)" shall mean the lowest reimbursement rate established by the State for (specific product).
- 1.10 "Medicaid Drug Rebate Agreement" shall mean the agreement in place between (name of provider) and the Secretary of Health and Human Services, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). CMS is the agency within HHS having the delegated authority to operate the Medicaid Program.
- 1.11 "Medicaid Recipient" shall mean any person enrolled in the State Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.
- 1.12 "Net Cost" shall mean the prescription drug ingredient reimbursement calculated as (AWP 11%) minus the sum of all rebates paid by (name of provider) to the State for the Covered Product for the calendar quarter. In the event of any change to the calculation used by the State to determine drug ingredient reimbursement paid by the State to Pharmacy providers, the applicable terms of this Agreement shall be amended to reflect such change.
- 1.13 **"Pharmacy"** shall mean a facility licensed to dispense legend drugs, and enrolled as a State Medicaid provider.
- 1.14 "Preferred Drug List" shall mean a document listing various pharmaceutical products covered by the State Medicaid Program for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products.
- 1.15 **"State Medicaid Program"** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients.
- 1.16 "State Supplemental Rebate" shall mean an amount paid on a calendar quarter basis by (name of provider) to State for utilization under State's fee for service Medicaid program pursuant to this Agreement which renders the net cost of Covered Products to be equivalent to the net cost Competitive Products on State Preferred Drug List.
- 1.17 "Unit" means a single capsule of Covered Product.
- 1.18 "USC" means the United States Code. All references in this agreement to USC chapters or sections shall include any successor, amended, or replacement statute.
- 1.19 "WAC" means the Washington Administrative Code. All references in this Contract to WAC chapters or sections shall include any successor, amended, or replacement regulation.

2. State Obligations

- 2.1 <u>Preferred Drug List.</u> To be eligible for the Supplemental Rebates specified in Attachment B:
 - a) State shall place and maintain Covered Product on the Preferred Drug List, it being agreed that utilization shall be eligible for the State Supplemental Rebate only in quarters in which Covered Product is listed on the Preferred Drug List; and
 - b) State shall place Covered Products in an advantaged position relative to nonpreferred Competitive Products regarding Preferred Drug List status, and
 - c) Neither State nor State's fiscal agent will in any way disadvantage Covered Product through usages or restrictions not equally applied to other PPIs on the Preferred Drug List.
 - d) State shall have on file the fully executed CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.
- 2.2 <u>Preferred Drug List Documentation and Publication.</u> State shall communicate the inclusion of Covered Product on the Preferred Drug List to State Medicaid Program providers through the standard notification process
- 2.3 <u>Invoicing.</u> State shall invoice (name of provider) for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS (Reconciliation of State Invoice format). State shall submit the State Supplemental Rebate invoice to (name of provider) within sixty (60) days after the end of each calendar quarter in which the Covered Product subject to such State Supplemental Rebate was paid for by State. Any amended invoice shall be submitted by State within fifteen (15) months after the end of the calendar quarter in which Covered Product was paid for by State.
- 2.4 <u>Patient Information.</u> State, its agents, employees and contractors shall not provide to (name of provider) any patient identifiable information or protected health information ("PHI") or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.
- 2.5 Approval of Generic PPI. If during the duration of this Agreement a generic equivalent of any Competitive Product should become available, State will allow Covered Product to remain on the Preferred Drug List so long as the net cost to the State, as defined in Attachment B, is not more than the lowest reimbursement cost as established by WAC 388-530-1300 for a generic equivalent.
- 2.6 <u>Competitive Product fluctuating net cost.</u> The net cost of (name of provider's)

 Covered Products to Washington will be less than or equal to the cost of the competitive product for each quarter covered by the terms of this contract.

- 3. (Name of Provider) Obligations
- 3.1 State Supplemental Rebate Payment. (Name of provider) agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid by the State and dispensed to Medicaid Recipients by Pharmacies for each calendar quarter that Covered Products are included in the Preferred Drug List. (Name of provider) shall pay to State the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. Nothing in this Agreement shall be construed to relieve (name of provider) from its obligation to pay Medicaid Drug Rebates for utilization by State Medicaid Recipients. State shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under its approved state plan.
- 3.2 <u>Payment Timeframe.</u> (Name of provider) shall pay to State the State Supplemental Rebate amount to which State is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days after receipt of State's invoice.
- 3.3 <u>Incomplete Submission.</u> (Name of provider) shall have no obligation to pay State Supplemental Rebate amounts for claims that are not submitted as part of an invoice in accordance with Section 2.3 of this Agreement. (Name of Provider) shall notify State or its designee of any incomplete submission within thirty-eight (38) days of (name of provider's) receipt of such submission pursuant to Section 2.3.
- 3.4 Over/Underpayment. If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally accepted applicable procedures followed by State or CMS in disputes concerning Medicaid Drug Rebates. Any overpayment shall be deducted from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, State will refund any such overpayment to (name of provider) within thirty (30) days of the parties' acknowledgement of the overpayment. (Name of provider) will remit any underpayment to State within thirty (30) days of the parties' acknowledgement of such underpayment.
- 3.5 <u>Discretion to Market.</u> Nothing in this Agreement shall be construed to prohibit (name of provider) from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that (name of provider) is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail Pharmacies and dispensed to Medicaid Recipients. If (name of provider) elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, (name of provider) shall make every reasonable effort to notify State prior to such actions.

4. Term and Termination

4.1 <u>Effective Date.</u> This Agreement shall be effective as of the date set forth by CMS in the CMS Exemption Letter, attached hereto as Exhibit C, and incorporated by reference, and shall continue in force through June 30, 2004, unless it is terminated sooner pursuant to the following:

- a) **Breach.** If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following delivery. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.
- b) Without Cause. Either party may terminate this Agreement without cause as of the end of any calendar quarter by giving the other party ninety (90) days prior written notice.
- 4.2 Accrued Obligations/Remedies. The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.
- 4.3 **Execution, Amendment, and Waiver.** This Agreement shall be binding only upon signature by both parties. This Agreement, or any provision, may be altered, amended, or waived by a written amendment executed by both parties.

5. Miscellaneous

- Record Keeping and Audit. During the term of this Agreement and for a period of three (3) years thereafter, both parties to the Agreement shall use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At (name of provider's) written request, State shall make such information available for inspection by (name of provider) representatives or its designated auditors during regular business hours. Upon written request, each party shall otherwise have the right to inspect, up to once each year, all such relevant books and records of the other party to verify compliance with the terms of this Agreement.
- 5.2 <u>Indemnification.</u> (Name of provider) shall be responsible for and shall indemnify and hold State harmless from all claims resulting from the acts or omissions of (name of provider) and any Subcontractor. State shall be responsible and shall indemnify and hold (name of provider) harmless from all claims resulting from the acts or omissions of State.
- 5.3 <u>Confidentiality.</u> Except as otherwise may be required to be disclosed by law and in accordance with the Rebate Agreement between the Secretary of Health and Human Services and the drug manufacturers, information disclosed by (name of provider) in connection with this Agreement will not be disclosed by the State Each party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of three (3) years thereafter
- 5.4 Notices. Any notice required or permitted to be given by either party to the other shall be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below.

(Name of Provider):	State:	
Mailing Address		_
	Attn:	_

- 5.5 Force Majeure. Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.
- Assignment. Neither party shall have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.
- 5.7 **No Waiver of Rights.** The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waiver any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.
- 5.8 **Entire Agreement.** This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) may not be amended or modified except upon the written agreement of both parties.
- 5.9 Governing Law. This Agreement shall be governed by the laws of the State of Washington. In the event of a lawsuit involving this Agreement, venue shall be proper only in Thurston County, Washington.
- Effect of Future Laws. In the event of the enactment, promulgation, rescission, modification or interpretation of any law or regulation after the date hereof which would (a) materially adversely affect the manner in which either party is obligated to perform under this Agreement, (b) adversely affect for either party the net prices or State Supplemental Rebates or other terms applicable under this Agreement, or (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party, each party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within sixty (60) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect.
- 5.11 <u>Compliance with Law.</u> In connection with its respective obligations under this Agreement, each party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

- 5.12 <u>Authority.</u> State and <u>(name of provider)</u> each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound.
- 5.13 <u>Best Price Contingency.</u> The effectiveness of this Agreement shall be contingent on (name of provider's) Best Price and AMP not being affected by State Supplemental Rebates.
- 5.14 <u>CMS Approval Contingency.</u> The effectiveness of this Agreement shall be contingent on receipt of CMS approval by State, as evidenced by the CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

(Name of Provider)	State of Washington Department of Social and Health Services	
Name	Name	
Title:	Title:	
Date:	Date:	

ATTACHMENT A

Covered Products

The products to which this Supplemental Rebate Agreement shall apply are the following:

NDC	Brand	Strength	Package Description

ATTACHMENT B

Rebate Formula

Supplemental Rebate shall be calculated on a calendar quarter basis according to the following formula and will be lower than or equal to the net cost of the Competitive Product:

Supplemental Rebate = ('Ingredient Reimbursement) – (2CMS Rebate) – (Net Cost)

First Quarter 2002 net cost for (name of product): Net Cost for (name/dosage of product) = (price) Net Cost for (name/dosage of product) = (price)

¹Ingredient Reimbursement based on the Average Wholesale Price (AWP) as published by First DataBank on the first day of a calendar quarter for the quarter in which the rebate applies;

²CMS Rebate as calculated and provided to State by CMS on a calendar quarter for the quarter in which the rebate applies.

ATTACHMENT C

CMS Exemption Letter

Supplement A to Attachment 4.19-B Page 1

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT State: Washington

REIMBURSEMENT FOR PHARMACY SERVICES

- I. General Information
 - A. Prescription drug reimbursement is based on (1) the standard 11-digit National Drug Code (NDC) (5-4-2 format), and (2) the quantity filled.
 - B. Total reimbursement for a prescription drug does not exceed the lowest of:
 - (1) Estimated acquisition cost (EAC) plus a dispensing fee;
 - (2) Maximum allowable cost (MAC) plus a dispensing fee;
 - (3) Federal Upper Limit (FUL) plus a dispensing fee;
 - (4) Actual acquisition cost (AAC) plus a dispensing fee for drugs purchased under section 340 B of the Public Health Services (PHS) Act and dispensed to medical assistance clients; or
 - (5) The provider's usual and customary charge to the non-Medicaid population.

II. Payment

- A. Providers must bill only after providing a service to an eligible client. Delivery of a service or product does not guarantee payment. For example, no payment is made when:
- The request for payment is not presented within the 365 day billing limit.
- The service or product is not medically necessary or is not covered;
- The client has third party coverage and the third party pays as much as or more than, the state allows for the service or product; or
- The service or product is covered in the managed care capitation rate.

TN# 02-001 Supercedes TN# ----- Approval Date:

SEP 1

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT State: Washington

REIMBURSEMENT FOR PHARMACY SERVICES (Cont.)

111. Tax

Tax is computed on items determined to be taxable according to the Washington State Department of Revenue.

IV. Estimated Acquisition Cost (EAC)

- First DataBank derives the Average Wholesale Price (AWP) of each product based on information they receive directly from each manufacturer or labeler. The appropriate percentage of the AWP that represents the Estimated Acquisition Cost (EAC) is determined. Most drugs are reimbursed at the EAC plus a dispensing fee.
- B. Currently applied EAC percentages are 89% of AWP for most drugs, including Schedule II drugs, and 100% of AWP for infusion/injectable drugs with certified AWPs.

Dispensing Fees V.

- A. A three-tier dispensing fee structure is used, with an adjusted fee allowed for pharmacies that participate in the Modified Unit Dose and/or True Unit Dose programs.
- B. Listed below are the dispensing fee allowances for pharmacies:

•	High-volume pharmacies (over 35,000 Rxs/yr)	\$4.20/Rx
	Mid-volume pharmacies (15,001-35,000 Rxs/yr)	
	Low volume pharmacies (15,000 Rxs/yr and under)	
	Unit Dose Systems	

C. A provider's dispensing fee is determined by the volume of prescriptions the pharmacy fills for medical assistance clients and the general public, as indicated on the annual prescription count survey distributed to pharmacies.

TN# 02-001 Effective Date: 1/1/02

Supercedes TN# -----